SAFER CONSUMER PRODUCTS PROPOSED REGULATIONS

SUMMARY OF CHANGES IN JULY 2012 PROPOSED REGULATIONS
(As compared with the October 2011 Informal Draft Regulations)

NOTE: *This is an informational non-inclusive summary of changes only. For a more precise understanding of the provisions of the proposed regulations, and how they differ from the October 2011 informal draft, please refer to the regulations themselves.*

Chemical—Product Prioritization

- Revisions have been made to the "list of lists" that will constitute the initial Chemicals of Concern (COCs) list: (i) the list will include ~1,200 COCs; and (ii) the lists selected for inclusion on the "list of lists" all meet certain criteria and provide a meaningful and beneficial addition.
- The regulations specify that the first list of Priority Products will contain no more than 5 product-chemical combinations.
- Prior to January 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more COCs that meet both of two criteria: (i) the COC is listed on the list of lists specified in the regulations because it exhibits one or more of seven hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity); and (ii) the COC is listed on one of the exposure indicator lists identified in the regulations for water quality, air quality, or biomonitoring.
- DTSC will issue a Priority Product Work Plan, by January 2014, that identifies the product categories that will be evaluated to identify products to be added to the Priority Products list during the next three years. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan. Additionally, DTSC will hold one or more public workshop to discuss candidate products prior to issuing the proposed Priority Products list for further public review and comment.
- The petition process has been augmented to allow petitions for: (i) *removal* of chemicals from the COC list (with some exceptions) and/or *removal* of products from the Priority Products list; (ii) requesting that an entire existing list of chemicals be added to the list of COCs; and (iii) requesting to establish/revise an alternatives analysis threshold for a COC in a Priority Product.
- Rather than considering a COC's or Priority Product's *potential* adverse impacts, DTSC will consider a COC's or Priority Product's *ability to contribute to or cause* adverse impacts. (Other uses of "potential' in the regulations have also been reworded.)
- The key prioritization factors for the product prioritization process have been streamlined.

- There is no longer an upfront exemption from the regulations for products regulated by other laws that provide protections with respect to the same public health and environmental adverse impacts and exposure pathways that are addressed by these regulations. Instead, this factor is taken into consideration during the product prioritization process.
- There will no longer be a mandate for how frequently DTSC must review and revise the COC list.

Alternatives Analyses Threshold Exemption

- The concentration-based trigger that determines whether a manufacturer can qualify for an exemption from the Alternative Analysis (AA) requirement has been renamed from "de minimis level" to *"alternative analysis threshold"*. The term "AA threshold" much better articulates the role and purpose of this concentration-based trigger.
- The regulations no longer specify a default AA threshold. Instead, DTSC will specify the AA threshold for each COC in a Priority Product as part of the Priority Product listing process. During the public comment period for a proposed Priority Product list, comments will be accepted on the proposed AA threshold for each proposed Priority Product.
- The regulations specify criteria to be used by DTSC when setting the AA threshold for each COC in a Priority Product. These include: (i) the ease or difficulty of removing the COC from the product if the COC is a contaminant rather than an ingredient; (ii) the detection limit for the COC; and (iii) various public health and environmental protection considerations. In no case, may DTSC specify an alternatives analysis threshold that is lower than the detection limit for the COC. If multiple COCs that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such COCs.
- The AA Threshold Notification provisions have been revised to eliminate requirements for information that would be difficult and/or costly for manufacturers to provide. Specifically, manufacturers will not be required to provide: (i) information describing attempts to eliminate/reduce the concentration of the COC in their Priority Product; or (ii) a demonstration that the COC in the Priority Product will not pose adverse impacts.

Alternatives Analyses

- The regulations no longer make a distinction between "assembled" and "formulated" products. When a product-chemical is added to the Priority Products list, DTSC will specify the component(s) and/or homogeneous material(s) within one or more components: (i) for purposes of the AA threshold calculation; and (ii) for specifying the minimum required focus of the AA. In some cases, this will be the product as a whole.

For a “highly durable product” (as defined in the regulation), DTSC will specify no more than 10 components and/or homogeneous materials per product every 3 years.

- Once a product is listed as a Priority Product, the manufacturer will be able to submit a Chemical of Concern Removal Notification (in lieu of an AA) if the only change to the product is the removal of the COC.
- An Abridged AA option will be provided if a manufacturer meets certain criteria to demonstrate that no viable alternative currently exists. Manufacturers choosing this route will be required to conduct a research and development project or fund a green chemistry challenge grant for the product, and may be subject to other regulatory responses.
- Manufacturers wishing to work with a consortium to conduct their AA will have the option of doing part of the AA on their own (so as to protect trade secrets).
- DTSC will have the option to allow a manufacturer up to 3 years to complete an AA (instead of the one year plus a one-year extension in the prior draft), if the manufacturer demonstrates that this amount of time is needed to comply with regulatory safety and/or performance testing requirements for multiple alternatives prior to choosing which alternative to pursue.
- The regulations make it clear that the AA due dates apply to the submission of the AA Reports, and that there is no due date for actual implementation of the AA decision (i.e., introducing the new product into the marketplace). Manufacturers will provide to DTSC an implementation plan, with key milestones and dates, for implementing the AA decision, and will notify DTSC once the new product has been introduced.
- If a manufacturer revises their alternative selection decision (either to retain the Priority Product or select a different alternative product) a revised AA Report must be submitted to DTSC.
- The economic impact analysis required as part of an AA has been revised to significantly reduce the scope of the externalized cost impacts that must be assessed.
- The requirement for identification of the manufacturing facility location in the AA has been removed.
- The experience requirement for certified assessors has been reduced from 4 years to 2 years.
- The conflict of interest standard for Accreditation Bodies has been revised to ensure problematic conflicts of interest are not allowed, while avoiding setting the “bar” unnecessarily so high that no organizations with the desired capabilities will be able to participate.

Regulatory Responses

- The regulations provide more guideposts for the circumstances under which specified regulatory responses (e.g., use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects) will be required, as well as principles and factors for DTSC to consider in selecting regulatory responses.
- The requirement to post product information at the point of sale is now an option, not a requirement.
- The requirement to implement an inventory recall (for a product subject to a sales ban) has been removed.

Other Changes

- Historic products and second-hand products are excluded from the definition of "consumer product" or "product".
- The exclusion for "bulk chemicals" has been eliminated. (To the extent appropriate, special considerations for bulk chemicals can be addressed when a product is listed as a Priority Product.)
- When the manufacturer/importer fails to comply with the AA or regulatory response requirement, retailers of the affected product will have 90 days (instead of 60 days) to comply with the requirement or notify DTSC that they have ceased ordering the product.
- The "Failure to Respond" list (which lists manufacturers who fail to provide information requested by DTSC) will be retitled, and expanded to also give credit to those manufacturers who do provide the requested information. The list will be called the "Response Status List" and will have three categories: (i) manufacturers who provide the requested information; (ii) manufacturers who do not provide the information but do respond with an adequate explanation as to why the information is not available; and (iii) manufacturers who fail to provide the requested information without adequately explaining why the information is not available.
- DTSC will also maintain on its website a Safer Consumer Products Partner Recognition List that identifies persons that have voluntarily provided DTSC with information that advances the quest for safer consumer products.
- The definition of "technically and economically feasible alternative" has been revised to: (i) remove consideration of externalized costs; (ii) take into consideration consumer acceptance after a phase-in period; and (iii) ensure that the manufacturer's operating margin is not significantly reduced.
- The definition of "functionally acceptable" has been revised to ensure that such an alternative would: (i) meet all applicable legal requirements; and (ii) be accepted by consumers.

- The definitions of “adverse public health impacts” and “sensitive subpopulations” have been revised to make it clear that occupational health impacts will be considered as part of public health impacts.
- All references to “mode of action” have been deleted.
- Exceedance of an enforceable California or federal regulatory public health or environmental standard has been added to the definitions of adverse public health and environmental impacts.
- Consideration of a chemical’s ability to degrade, form reaction products, or metabolize into another chemical has been incorporated into the regulations.
- The administrative dispute procedure will not be available for actions taken by DTSC to list chemicals, act on petitions, or respond to claims of trade secret protection.
- The amount of time for requesting informal dispute resolution has been increased from 15 days to 30 days.
- The regulations will give DTSC the option to establish a public comment period of longer than 45 days for the proposed chemicals and products lists and proposed regulatory response determinations.
- If DTSC is unable to complete the review of an AA Report and issue a notice of compliance or deficiency within 60 days, DTSC will issue a notice of ongoing review specifying the estimated date by with DTSC expects to complete its review.
- The regulations have been revised to clarify the provision (required by the statute) that trade secret protection may not be claimed for hazard trait submission information.